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| 10/021,407 | 12/12/2001 | Edward A. Rhad | END-795 | 3685 |
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| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | EXAMINER FOREMAN, JONATHAN M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | 80 |
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,407

Applicant(s)

RHAD ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 12/2/03 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 5 – 8, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation related to the material being “spaced longitudinally from said side port of said needle” is not described in the specification. Page 11, lines 20 – 22 states that the “artifact indicates the orientation of the elongated needle 30 relative to the sight of biopsy, and where the tissue receiving bowl begins...”. One having ordinary skill in the art would understand this to mean that the material is adjacent to the side port and not longitudinally spaced from the side port.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5 - 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0040671 to Somogyi et al. in view of U.S. Patent No. 5,782,764 to Werne.

In reference to claim 5, Somogyi et al. discloses a biopsy device (Figure 7A) a substantially tubular needle (701) having a distal end, a proximal end (707), and a longitudinal axis therebetween, a side port (705) spaced from the distal end on the needle for receiving a tissue sample [0047]; and a closed distal tip having a hollow cavity partially filled with a material (703). The material disclosed by Somogyi et al. will leave an artifact under MRI [0033]. However, Somogyi et al. fails to disclose the needle being formed of a non-metallic material or having a sharpened tip. Werne teaches a biopsy device compatible for use with a MRI machine wherein the needle is formed of a non-metallic material (Col. 8, lines 36 - 65) and has a sharpened distal tip (40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle as disclosed by Somogyi et al. to have a sharpened tip and to be formed of a non-metallic material as taught by Werne in order to better penetrate tissue and to not distort or degrade the images obtained with an MRI machine while performing a biopsy procedure.

5. In reference to claims 6, 7 and 8, Werne discloses the needle comprising a glass fiber reinforced polymer resin (Col. 8, lines 36 - 65), but fails to disclose the needle comprising a thermoplastic. However it would have been obvious to one having ordinary skill in the art to form the needle of any material that meets the desired function, such as a thermoplastic. Additionally, it would have been obvious to one having ordinary skill in the art to use any material which leaves an artifact as desired. The selection of a known material based upon its suitability for the intended use

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is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

6. Claims 5, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0040671 to Somogyi et al. in view of U.S. Patent Application Publication No. 2002/0082519 to Miller et al.

In reference to claims 5, 13 and 14, Somogyi et al. discloses a biopsy device (Figure 7A) a substantially tubular needle (701) having a distal end, a proximal end (707), and a longitudinal axis therebetween, a side port (705) spaced from the distal end on the needle for receiving a tissue sample [0047]; and a closed distal tip having a hollow cavity partially filled with a material (703). The material disclosed by Somogyi et al. will leave an artifact under MRI [0033]. However, Somogyi et al. fails to disclose the needle being formed of a non-metallic material, having a sharpened tip or having a cutter movable in the needle. Miller et al. discloses a biopsy device having a needle formed of a non-metallic material [0062], having a sharpened tip (16) and having a cutter (17) movable in the needle [0058]. It would have been obvious to one having ordinary skill in the art to modify the needle as disclosed by Somogyi et al. to be formed of a non-metallic material, to include a sharpened tip and a cutter movable in the needle, as taught by Somogyi et al., in order to make the needle compatible with MRI so the margins of the tumor can be viewed during the biopsy procedure [0020], to allow the tip to penetrate body tissue [0057] and to remove a portion of the tumor once it has entered into the side port.

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,299,593 to Wakabayshi.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF

February 13, 2004



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700